

REMARKS

Claims 1-9, 12-13, 15-18, 20-23, 31-32, 34-37, and 50 are pending in this application.

Claims 10, 19, 24, and 26-29 are cancelled in this paper without prejudice to Applicant's right to pursue the subject matter recited by them in one or more divisional, continuation, or continuation-in-part applications.

Claims 1 and 12-13 have been amended; support for these amended claims can be found throughout United States Patent Application Publication No. 2004/0171147 A1 (hereinafter "the present application") at, for example, paragraphs [0011]-[0013] and [0019]-[0022] and [0039] and [0043].

Claims 18 and 20-23 have been amended; support for these amended claims can be found throughout the present application at, for example, paragraphs [0039] and [0043] and [0047] and [0050] and [0060]-[0062].

Claims 31-32 have been amended; support for these amended claims can be found throughout the present application at, for example, paragraph [0018] and [0039] and [0043] and [0047] and [0050] and [0060]-[0062].

Claims 34, 35, and 37 have been amended; support for these amended claims can be found throughout the present application at, for example, paragraphs [0019] and [0039] and [0043].

Claim 50 has been amended; support for this amended claim can be found throughout the present application at, for example, [0011]-[0013], [0019]-[0022], [0039], [0042]-[0043], [0060]-[0062], and original claim 50.

No new matter has been added.

Alleged New Matter Rejections

At paragraph 3 of the Advisory Action, the Examiner contends that certain amendments constitute "new matter." Applicant respectfully traverses.

Contrary to the Examiner's contentions, the present application does, in fact, provide support for the amendments to claims 20 and 34. Specifically, for example, the present application provides support for the combination of units and certifications at, for example, paragraphs [0015], [0039], and original claims 23-24. In addition, the present application provides support for the amendments to claim 23 at, for example,

original claim 16, original claim 23, original claim 24, and paragraphs [0014]-[0015], [0023], and [0048].

As such, Applicant respectfully requests that the rejections based upon the alleged “new matter” be reconsidered and withdrawn.

The Rejection Under 35 U.S.C. § 112, ¶2 Should Be Withdrawn

On page 2 of the Office Action, claim 34 is rejected as allegedly indefinite. In particular, the Examiner points to the allegedly vague and indefinite use of “derived from” in claim 34. Without acquiescing to the rejection of the Examiner, and solely in order to promote the progress of the present application, Applicant has amended claim 34. As such, Applicant respectfully requests that the rejection under 35 U.S.C. § 112, ¶2 be reconsidered and withdrawn.

The Rejections Under 35 U.S.C. § 112, ¶1 Should Be Withdrawn

On pages 3-6 of the Office Action, claims 1-10, 12-13, 15-24, 26-29, 31-32, 34-37, and 50 are rejected as allegedly not enabled. The Examiner relates three basic propositions. First, it is alleged that the claims are not enabled because a skilled artisan would purportedly “have to conduct trial and error experimentation for each combination of plurality of cells” and “possibly for each individual in need of treatment.” Office Action at page 5. In addition, the Examiner asserts that the issue at hand is “whether the instant specification has taught how to make or use a cytotherapeutic unit with any type of cells ... for ANY disease state....” *Id.* Further, the Examiner contends that “the ability to make and effectively use the claimed unit for human therapeutics is unpredictable.” *Id.* at page 6. Applicant respectfully traverses these rejections in their entirety.

Without acquiescing to the Examiner’s rejection, and solely to promote the progress of the present application, Applicant has deleted claims 10, 19, 24, and 26-29. As clearly noted above, Applicant has done so without prejudice to Applicant’s right to pursue the subject matter recited by them in one or more divisional, continuation, or continuation-in-part applications.

Applicant respectfully points out that independent claims 1, 18, 31, 34, and 50, as they currently stand, recite cytotherapeutic units and libraries comprising the same. As such, Applicant respectfully points out that whether the cytotherapeutic units represent “therapy for ANY disease state” is wholly irrelevant to the enablement of

the pending claims. In this regard, Applicant points out that the present application provides information sufficient to enable those of ordinary skill in the art to make and use the claimed cytotherapeutic units and libraries.

The present application clearly establishes at paragraphs [0060]-[0062] that the claimed units and libraries, useful for treating at least three (3) diseases and conditions, are encompassed by the present invention. Certain methods of making the claimed units and libraries are provided at paragraphs [0011]-[0013] and [0019]-[0022] and [0039] and [0042]-[0043]. It is also provided at paragraphs [0060]-[0062] that the claimed units can be transplanted. Exemplary doses are disclosed at paragraph [0039].

In any event, the Examiner has admitted on the record that the present application is "enabling for a cytotherapeutic unit comprised of CD34+ and CD8+ cells for treatment of patients in need of hematopoietic cells." Office Action at page 3. As the Examiner admits, the present application clearly enables those of ordinary skill in the art to make and use at least one embodiment¹ of the presently claimed inventions. For at least this reason alone, certain pending claims- reciting limitations consistent with the Examiner's admission- should be allowed.

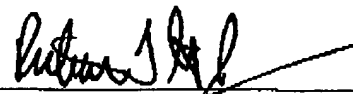
As such, Applicant respectfully requests reconsideration and withdrawal of the present rejections under 35 U.S.C. § 112, ¶1.

In sum, Applicant respectfully requests that the Examiner consider the present remarks and reconsider and withdraw all pending rejections. Should there be any further matters requiring consideration, the Examiner is invited to contact the undersigned counsel.

¹ Naturally, Applicant maintains that multiple embodiments and multiple inventions (such as, for example, embodiments and inventions not presently claimed) are supported by the present application.

Respectfully submitted,

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